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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/888,990 | 06/26/2001 | Solo Goldstein | ADIR359/Iw | 9535 |

25666 7590 09/23/2003

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| EXAMINER |
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ROBINSON, BINTA M

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| ART UNIT | PAPER NUMBER |
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1625

DATE MAILED: 09/23/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/888,990

Applicant(s)

GOLDSTEIN ET AL.

Examiner

Binta M. Robinson

Art Unit

1625

-- The MAILING DATE of this communication appears on th cover sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 19-29 and 31-36 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: .

Detailed Action

The 112, second paragraph rejection of claims 35-36 are rendered moot in light of applicant's cancellation of these claims.

The applicant traverses the restriction requirement made at paper no. 10, alleging that a chemist would not find the invention to comprise structurally distinct inventions. However, the applicant is claiming a compound where radicals such as Y in the compound of formula I can be as any heteroaryl ring, or R3 and R4 in A can come together with the nitrogen carrying them to form any monocyclic or bicyclic system that can range in size from 3 to 10 carbon systems. Such a genus contains several structurally distinct inventions as is evidenced by the various classifications that these inventions fall into such as 549, 546, and 548. In the instant case the different inventions have achieved a separate status in the art, have separate fields that aren't coextensive, and are capable of supporting separate patents. Further, a prior art reference that would anticipate the claims under 35 USC 102(b) would not render obvious the same claim(s) under 35 U. S. C. 103 (a) with respect to another member. Searching the entire genus would be a burden on the USPTO in terms of time and expense. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. The restriction requirement is FINAL.

(Old rejection)

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1625

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19-29 and 31-36 in part are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the radicals, R1 and R2 forming together with the nitrogen carrying them all 5 to 7 membered saturated carboxylic system, Y equal to all heteroaryl-(C1-C6)alkyl, R3 and R4 forming together with the nitrogen carrying them a monocyclic, or bicyclic (C3-C10 system) and A equal to all heteroaryl rings. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte* Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

Claim(s) 31 in part is rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The disease being treated by treating a condition where specific nicotinic ligands of alpha4beta2 receptors are not specifically

Art Unit: 1625

stated. The specification must contain one practical utility in currently available form.

The inhibition of an enzyme must be related to a disease that needs to be improved and this disease needs to be recited. There is no reasonable assurance that these compounds will have all of the alleged properties or have the applicants supplied the supporting data. The applicant is referred to *In re Fouche* 169 USPQ 429 ccpa, 1971, MPEP 716.02 B. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte Foreman* 230 USPQ 546 (Bd. Of App. And Inter 1986).

Claim 32 in part is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of treating all of the various diseases claimed, many of which are unrelated.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Art Unit: 1625

In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not indicate which compounds were tested in pharmacological studies.

In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Claim 30 in part is objected to because it is based on a rejected claim.

Response to Applicant's Remarks

The applicant traverses the 112, first paragraph enablement rejection of claims 19-29 and 31-36 alleging that "R1 and R2 forming together with nitrogen carrying them all 5 to 7 membered saturated carbocyclic systems, Y equal to all heteroaryl (C1-C6)alkyl, R3 and R4 forming together with the nitrogen carrying them a monocyclic, or bicyclic (C3-C10 system) and A equal to all heteroaryl rings" is not in the elected Group I. However, this phrase is still present in the claims, as the applicant has not narrowed the claims to the elected subject matter. There is no reasonable assurance that the different heterocyclic ring systems combined would have the alleged utilities. See *In re Fouche*, USPQ 429 (CCPA 1971). There is not sufficient exemplification to show that all of the ring systems could be attained synthetically without description or exemplification.

The applicant alleges that claim 31 is rejected under 112, first paragraph for indefiniteness. Actually, claim 31, is rejected under 35 USC first paragraph, for lack of asserted utility, not

Art Unit: 1625

indefiniteness. The applicant also traverses the 112, first paragraph rejection of claim 32. The declaration submitted December 18, 2002 does not overcome this rejection because the claims still do not claim specific diseases rather than mechanisms. The applicants have not shown through their own experimental data the effects of their compounds on the diseases alleged to be related to the mechanism being treated. T

The applicant's declaration has been considered, but is not a showing that is commensurate with the scope of the claims and thus does not overcome the 112, first paragraph rejections. See in re Lindner 173 USPQ 356 (ccpa 1973).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).


Art Unit: 1625

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson


September 22, 2003


ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600